

## **REMARKS**

Independent claims 1 and 92 have been amended to distinguish over the prior art of record, and new claims 97-100 have been added. No new matter was added. Accordingly, claims 1, 2, 9, 10, 15, 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 54, 58, 60-89 and 92-100 are pending. For reasons discussed in greater detail below, Applicants respectfully submit that the present application is in condition for allowance.

Applicants respectfully note that no additional claim fees are believed to be due with the filing of this Amendment. The present application was initially filed with 65 claims in total, and the fee for 45 extra claims over 20 was submitted to the U.S. Patent and Trademark Office at the time of national phase entry. The pending claims as a result of this Amendment include 63 claims in total with 3 claims being independent.

### **I. Claim Rejections - 35 USC §102(e)**

In the Office Action, the Examiner rejects claims 1, 2, 9 and 10 under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,130,098 issued to Handique et al.

As discussed in Applicants' previous Amendment, Handique et al. disclose the use of a hydrophobic surface region along an intermediate portion of an otherwise hydrophilic microchannel. For instance, see the location of hydrophobic region (40) illustrated in FIG. 3A of the Handique patent. The hydrophobic surface region is used to regulate flow of a liquid sample between one part of a microchannel structure and another.

More specifically, the hydrophobic region (40) of Handique et al. is located a spaced distance from the outer end of inflow channel (20) that communicates with an exterior of the apparatus. At column 14, lines 26-29, the Handique et al. patent states that "liquid (shown as a horizontal dashed line) placed at the inlet (20) is drawn in by surface forces and stops in the channel at hydrophobic region (40)". Thus, the aqueous liquid sample enters the Handique et al. microchannel structure by being automatically drawn into the microchannel by surface forces as soon as the liquid sample contacts the inflow channel (20). Thereafter, the hydrophobic region (40) regulates further passage of the aqueous fluid along the length of the microchannel. However, the regulating function of the hydrophobic region occurs only after the aqueous fluid penetrates the microchannel structure.

In contrast, independent claim 1, as amended, of the present application requires the inflow channel to have an outer end communicating with an exterior of the apparatus and a hydrophobic inner surface that extends from the outer end towards the reaction chamber. No new matter was added. For example, see FIG. 1A of the present application in which a drop of an aqueous fluid is seated on the outer end of the inflow channel. FIG. 1A also clearly identifies the hydrophobic walls of the inflow channel extending from the outer end to the inner end and interconnecting to the reaction chamber, or "Microreactor".

A claim of a patent application can be anticipated under 35 USC §102 only if each and every element is found described in a single prior art reference. The identical invention must be shown in as complete detail as contained in the claim. The elements identified by the reference must be arranged as required by the claim. If a prior art reference relied on in a rejection made

under §102 does not contain every element recited in the claim in as complete detail as is contained in the claim and arranged as recited in the claim, the rejection is improper.

Applicants respectfully submit that the Handique patent fails to disclose an inflow channel having a hydrophobic surface at an outer end that communicates with an exterior of the device. For this reason, Applicants respectfully submit that the §102 rejection is unsupported by Handique et al. and should be withdrawn.

New independent claim 97 includes all the limitations of independent claim 1, discussed above. Accordingly, claim 97 is not anticipated by Handique et al. for the same reason.

## **II. Claim Rejections - 35 USC §103(a)**

- A. In the Office Action, the Examiner rejects claims 9, 10, 60-63 and 65-71 under 35 USC §103(a) as being obvious over U.S. Patent No. 6,130,098 issued to Handique et al.

As discussed above with respect to the §102(e) rejection, independent claim 1, as amended, of the present application requires the hydrophobic surface, or gate means, to extend from the outer end of the inflow channel and to communicate with an exterior of the apparatus. Applicants respectfully submit that Handique et al. fail to disclose, suggest or teach such a structural configuration and fail to provide the motivation for making such a modification. In addition, Applicants submit that the structural configuration of the present application is patentable and provides a significant advantage over the structure of the device disclosed by the Handique et al. patent.

As discussed above, the inflow channel (20) of Handique et al. has a surface that automatically draws an amount of aqueous liquid sample into the microchannel. A hydrophobic

region (40) located only at an intermediate position along the length of the microchannel regulates flow of a liquid sample from one part of the microchannel to the next. The hydrophobic regions of Handique et al. are formed by chemical modification of surfaces of the microchannel

In contrast, the hydrophobic walls at the outer end of the inflow channel required by claim 1 of the present application form a hydrophobic gate and prevent entry of any amount of an aqueous fluid into the microchannel structure of the apparatus until acted upon by a fluid entry force. Thus, the structure of the present invention enables precise control as to when, and if, an aqueous fluid positioned adjacent the inflow channel is permitted to penetrate and enter any portion of the microchannel. A fluid entry force is applied only when a drop of the desired aqueous fluid is properly located adjacent the outer end of the inflow channel. This enables the user to prevent contaminants from entering the microchannel structure and from disrupting the assay.

The structure of the present invention is recited in more detail by new claims 97-100 of the present application. These claims require a "reaction chamber" to be defined by walls. Some of the walls are formed of a first material and some are formed of a different second material. Independent claim 97 requires the second material to be a hydrophobic material and requires a fluid inflow channel to extend transversely through the hydrophobic material such that the hydrophobic walls of the inflow channel provide a gate means. Claim 98 requires the device to include a separate overlying layer laminated to a substrate. The substrate and overlying layer are required to form the walls of the reaction chamber, and the substrate is required to be made of the first material while the overlying layer is required to be made of the hydrophobic material. Claim

99 requires the substrate to have a depression which defines the bottom and sides of the reaction chamber with a top wall of the reaction chamber being provided by the hydrophobic overlying layer. Claim 100 provides specific examples of the first material and hydrophobic material. No new matter was added. For example, see page 9, lines 7-37; page 12, line 21, to page 13, line 16; and FIGs. 1A and 1B of the present application, as filed.

Accordingly, Applicants respectfully submit that Handique et al. fail to disclose, teach or suggest an inflow channel having a hydrophobic surface at an outer end that communicates with an exterior of the device. In addition, Applicants respectfully submit the Handique et al. fail to disclose, teach or suggest the structure of an inflow channel that enables prevention of entry of any aqueous fluid into the apparatus and microchannel until a fluid entry force is applied to permit fluid flow through the fluid inflow channel. Further, with respect to claims 97-100, Handique et al. fail to disclose, teach or suggest a laminate structure having a fluid sample inflow channel extending transversely through a hydrophobic layer overlying a reaction chamber formed in an underlying substrate.

For the above stated reasons, Applicants respectfully submit that claims 9, 10, 60-63 and 65-71, which all depend directly or indirectly from claim 1, are non-obvious and patentable over the Handique et al. patent. New claims 97-100 are also submitted as being non-obvious and patentable over the Handique et al. patent.

- B. In the Office Action, the Examiner rejects claims 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 54, 58, 64, 72-89 and 92-96 under 35 USC §103(a) as being obvious over U.S. Patent No. 6,130,098 issued to Handique et al. in view of U.S. Patent No. 6,709,869 B2 issued to Mian et al.

Mian et al. fail to disclose the use of a hydrophobic gate region in connection with controlling the transport of liquid samples through a microchannel. Accordingly, for the same reasons discussed above for the patentability of independent claim 1 over the Handique et al. patent, Applicants respectfully submit that the combination of Handique et al and Mian et al. fail to obviate independent claim 1 and 92. The references fail to disclose, teach or suggest an inflow channel having a hydrophobic surface at an outer end that communicates with an exterior of the device. The references also fail to disclose, teach or suggest the structure of an inflow channel that enables prevention of entry of any aqueous fluid into the apparatus and microchannel until a fluid entry force is applied to permit fluid flow through the fluid inflow channel. Further, the references fail to disclose, teach or suggest a laminate structure having a fluid sample inflow channel extending transversely through a hydrophobic layer overlying a reaction chamber formed in an underlying substrate.

Accordingly, Applicants submit that claims 16, 19, 22, 23, 25-29, 31, 33, 36, 38, 41, 42, 44, 46, 54, 58, 64, 72-89 and 92-96 of the present application are patentable over the cited combination of references.

### **III. Conclusion**

In view of the above amendments and remarks, Applicants respectfully submit that the rejections have been overcome and that the present application is in condition for allowance.

Thus, a favorable action on the merits is therefore requested.

Please charge any deficiency or credit any overpayment for entering this Amendment to our deposit account no. 08-3040.

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